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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

BEATRICE MILLS,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and SANOFI-SYNTHELABO, INC.,

Defendants.

Case No. 2:11-CV-00968-FJM

DEFENDANTS' MOTION TO DISMISS PURSUANT TO FEDERAL RULES 12(c), 8(a), AND 9(b), AND ACCOMPANYING BRIEF

ORAL ARGUMENT REQUESTED

Plaintiff's First Amended Complaint (the "Complaint"), which seeks damages for injuries Plaintiff allegedly suffered as a result of taking the prescription medication Plavix®, consists almost entirely of sweeping, conclusory allegations that should be given no weight under the Supreme Court's holdings in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, __ U.S. __, 129 S. Ct. 1937 (2009). Stripped of those conclusory allegations, the Complaint references only a few decade-old FDA letters about Plavix® promotional materials and two medical journal articles that investigated use of the drug in specific types of patients. Plaintiff's Complaint says ***nothing*** about how the promotional materials or the articles relate to ***this*** Plaintiff's Plavix® prescription or alleged injuries. The few factual allegations about purportedly misleading promotional

efforts fail to support the diverse legal theories Plaintiff asserts, which range from strict products liability and emotional distress claims to negligence, fraud, and warranty claims. As a result of these deficiencies, Plaintiff has not pled sufficient facts to support any of her claims, and the Court should dismiss the Complaint.

FACTUAL BACKGROUND

A. Plavix®

Plavix® (clopidogrel bisulfate) works by inhibiting blood platelets from forming clots. Physicians widely prescribe the drug to reduce the risk of heart attacks or strokes in certain patients.[1] The U.S. Food and Drug Administration ("FDA") has approved Plavix® for use as monotherapy (*i.e.*, without aspirin) in patients with recent heart attack or stroke or diagnosed peripheral arterial disease ("PAD").[2] After studies demonstrated that Plavix® had other clinical benefits, FDA approved Plavix® for dual therapy with aspirin for the treatment of patients with particular types of acute coronary syndrome ("ACS").[3] ACS is a set of clinical signs and symptoms occurring when the heart muscle does not get enough blood due to plaque narrowing or blocking the arteries leading to the heart.

Plavix® has become a mainstay of antiplatelet therapy. Dual therapy of Plavix®

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[1] We provide publicly available information in this section to give the Court background on the issues raised by the Complaint, even though it is not necessary to consider this information as "fact" to resolve this motion to dismiss. In any event, the Court may consider publicly available information without converting this motion into one for summary judgment. *See, e.g.*, *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) ("A court may take judicial notice of 'matters of public record' without converting a motion to dismiss into a motion for summary judgment." (citing *MGIC Indem. Corp. v. Weisman*, 803 F. 2d 500, 504 (9th Cir. 1986)); *Ariz. Minority Coal. for Fair Redistricting v. Ariz. Indep. Redistricting Comm'n*, 366 F. Supp. 2d 887, 895 (D. Ariz. 2005) (same); *Hall v. Bristol-Myers Squibb Co.*, No. 06-5203 (FLW), 2009 WL 5206144, at *6 (D.N.J. Dec. 30, 2009) (finding that FDA letters and copies of pharmaceutical studies, attached as exhibits to a motion to dismiss, were properly before the court). For the reasons explained below, Plaintiff's Complaint is facially deficient irrespective of whether the Court considers such information.

[2] *See* 2007 Plavix® label (Ex. A). The Plavix® label is a publicly available document that can be considered on a motion to dismiss. *See supra* note 1; *see also Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 776-77 (W.D.N.C. 2008) (pharmaceutical package insert considered on a motion to dismiss a failure to warn claim); *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 500-01 (D.N.J. 2006) (drug packaging insert considered on a motion to dismiss a consumer fraud claim).

[3] *See* Ex. A.

plus aspirin has been for many years the standard of care for treatment of patients with ACS, as well as with the placement of stents (medical devices that are commonly implanted to keep patients' arteries open but that can also trigger clotting). Leading medical consensus organizations have recommended Plavix® in these and other clinical settings and continue to do so today.[4]

Because it functions by inhibiting blood clotting, Plavix®, like all antiplatelet therapy, increases the risk of bleeding. That well-known risk has been described in the product labeling at all relevant times.[5]

B. Plaintiff's Complaint

Plaintiff filed her Complaint in the Superior Court for the State of Arizona in and for the County of Maricopa on January 19, 2011, against Defendants Bristol-Myers Squibb Company, Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis, U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"). Defendants timely removed this action to federal court pursuant to 28 U.S.C. §§ 1332, 1441, and 1446.

The Complaint includes a "Facts Common to All Counts" section that purports to assert the basis for Defendants' liability for Plaintiff's alleged causes of action. Yet allegations regarding her injury are set forth in just one paragraph of the 123-paragraph Complaint, in which she claims that she was first prescribed Plavix® on or about January 7, 2009; "began to hemorrhage" on January 12, 2009; and was re-admitted to the hospital later that same month "for continual problems relating to clotting and bleeding." First Am. Compl. ¶ 31. Only ***seven paragraphs*** of the Complaint delineate ***facts*** alleging supposed wrongdoing by Defendants (as opposed to boilerplate legal conclusions). Even these few factual allegations have no connection to this Plaintiff and therefore cannot serve as a basis for liability.

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[4] *See, e.g.,* Frederick G. Kushner et al., *2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction*, 54 J. Am. C. Cardiology 2205, 2212 (2009), *available at* http://content.onlinejacc.org/cgi/reprint/54/23/2205.pdf.

[5] *See* Ex. A. The label attached as Exhibit A is the label in place in January 2009, when Plaintiff allegedly was first prescribed Plavix®. *See* First Am. Compl. ¶ 31.

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Four of these paragraphs (¶¶ 19-22) reference three FDA letters, dated 1998 and 2001, regarding Plavix® promotional materials. Plaintiff does not allege that she or her prescribing doctors actually saw, let alone relied on, ***any*** of these materials. In fact, Plaintiff's first prescription for Plavix® allegedly occurred in 2009, *see id.* ¶ 31, post-dating the letters she cites by several years. Nor does Plaintiff claim -- or provide any basis to conclude -- that these materials are representative of promotional materials relevant to the indications for which Plaintiff took Plavix®.

The other three paragraphs of factual allegations (¶¶ 27-29) reference two out of the hundreds of published articles on Plavix®. Even accepting Plaintiff's characterizations of the studies, ***no*** allegations link these studies to Plaintiff's use of Plavix® or her alleged injuries. For instance, the Chan study (as described by Plaintiff), "compared the effects of Aspirin and Plavix on patients ***who had previously had stomach ulcers that had healed***" and found more ***stomach*** bleeding with Plavix®. *Id.* ¶ 27.[6] The Complaint, however, does not allege that Plaintiff had a previously healed stomach ulcer at the time of her Plavix® use or that Plaintiff experienced ***stomach*** bleeding.

Plaintiff similarly alleges no connection between the CHARISMA study and Plaintiff's injuries or Plavix® prescription. CHARISMA examined a specific proposed new indication for the drug: the potential use of Plavix® plus aspirin in patients with no previously approved indications for Plavix® use such as ACS or PAD.[7] As Plaintiff describes it, CHARISMA "found that ***Plavix plus aspirin (dual therapy)*** is only

[6] Although the Court need not address the accuracy of Plaintiff's allegations about the studies on this motion to dismiss, we note that Plaintiff incorrectly describes the Chan study as "compar[ing] the effects of Aspirin and Plavix on patients" and showing "the fallacy of Defendants' assertion that Plavix is safer and more effective" than aspirin. *See* First Am. Compl. ¶ 27. The Chan study was not a direct comparison of aspirin to Plavix®. As the study's title indicates, the group of patients given aspirin in that study were also give a stomach acid reducer (known as a PPI), while the patients on Plavix® received no PPI. *See* Francis Chan et al., *Clopidogrel Versus Aspirin and Esomeprazole to Prevent Recurrent Ulcer Bleeding*, 352 New Eng. J. Med. 238, 238 (2005). As noted above, *see* note 1 *supra*, the Court may consider such matters of public record on a motion to dismiss.

[7] *See* Deepak L. Bhatt et al., *Clopidogrel and Aspirin versus Aspirin Alone for the Prevention of Atherothrombotic Events*, 354 New Eng. J. Med. 1706 (2006).

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minimally more effective than aspirin plus placebo at preventing artherothrombotic events" and that "***in those patients without ACS or PAD***, dual therapy with aspirin and Plavix does more harm than good." *Id.* ¶ 29 (emphasis added). But the Complaint does not allege that Plaintiff actually was prescribed Plavix® for a condition other than ACS or PAD. It does not even allege that Plaintiff took dual therapy with aspirin. The Complaint says nothing whatsoever about the reason Plaintiff was prescribed Plavix®.

Plaintiff's Complaint thus does not explain how the Chan study or the CHARISMA study reflect any wrongdoing by Defendants. Plaintiff offers vague innuendo that Defendants improperly promoted Plavix® in light of these studies, but the Complaint pleads ***no*** facts identifying any particular misleading or inappropriate promotional activities relating to either study or to Plaintiff.[8]

In fact, a New Jersey federal district court already has found these same allegations lacking. Plaintiff appears to have copied her "Facts Common to All Counts" largely verbatim from twenty-three complaints filed in the United States District Court for the District of New Jersey (the "New Jersey Court") in 2006 and 2007. *Compare*, *e.g.*, First Am. Compl. ¶¶ 10-31, *with* First Am. Compl. ¶¶ 10-31, *Street v. Bristol-Myers Squibb Co.*, Civil Action No. 3:07-cv-1182 (FLW) (D.N.J. May 1, 2009) (Ex. B). The New Jersey plaintiffs geared their allegations toward consumer fraud and negligent misrepresentation claims, and the New Jersey Court granted Defendants' motion to dismiss those claims. *See*, *e.g.*, First Am. Compl. ¶¶ 80-111, *Street*; *Street v. Bristol-Myers Squibb Co.*, No. 3:07-cv-1182 (FLW), 2009 WL 5216989, at *1 (D.N.J. Dec. 30, 2009). The New Jersey Court explained that:

> With regard to their own experiences, or that of Plaintiffs' prescribing physicians, in connection with Defendants' purported false and misleading promotional materials and practices, Plaintiffs' Amended Complaints are silent. . . .

[8] Plaintiff's allegations that FDA granted Plavix® priority regulatory review, *see* First Am. Compl. ¶ 12, and that Plavix® had significant sales, *see id.* ¶ 17, do not suggest any wrongdoing. If anything, FDA's determination that Plavix® warranted priority review and doctors' frequent prescriptions of Plavix® for their patients undermine Plaintiff's allegations that Plavix® is an inferior drug.

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> The conclusory nature of Plaintiffs' allegations mandates dismissal. . . . Here, Plaintiffs have failed to plead ***any*** facts which could support a nexus between the purported deceptive practices and Plaintiffs' injuries. While Plaintiffs make exhaustive allegations regarding Defendants' alleged illegal practices by relying on FDA correspondence and scientific studies, the FAC fails to allege any facts linking Defendants' conduct with Plaintiffs' resultant injuries. Plaintiffs fail to identify any specific advertisements that were viewed by themselves or their prescribing physicians.

Id. at *10-11 (emphasis in original). Plaintiff's Complaint here is defective for essentially the same reason: the Complaint fails to supply any allegations connecting the sparse factual allegations concerning over-promotion to ***this*** Plaintiff's prescription for Plavix®. As with the New Jersey complaints, which focused on allegedly misleading promotional activity, Plaintiff's common law fraud, negligent misrepresentation, and fraud claims are nowhere linked to Defendants' alleged conduct and should be dismissed for the same reasons the claims were dismissed by the New Jersey Court.

ARGUMENT

I. RECENT SUPREME COURT PRECEDENT REQUIRES A RIGOROUS ASSESSMENT OF PLEADING SUFFICIENCY

Four years ago, in *Bell Atlantic Corp. v. Twombly*, the Supreme Court clarified the pleading standard a plaintiff must meet under Federal Rule of Civil Procedure 8(a). In dismissing the antitrust claims at issue, the Court held that a plaintiff may not rely on conclusory allegations. Rather, "Rule 8(a) 'contemplate[s] the statement of circumstances, occurrences, and events in support of the claim presented' and does not authorize a pleader's 'bare averment that he wants relief and is entitled to it.'" *Twombly*, 550 U.S. at 566 n.3 (citation omitted). To meet the standard under *Twombly*, a plaintiff must therefore allege "more than labels and conclusions" and more than "a formulaic recitation of the elements" of a claim. *Id.* at 555-56. A complaint, in short, must "possess enough heft to show that the pleader is entitled to relief." *Id.* at 557 (quotation omitted).

More recently, in *Ashcroft v. Iqbal*, the Supreme Court made clear that the pleading standard announced in *Twombly* applies outside of the antitrust context. *See Iqbal*, 129 S.

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Ct. at 1953 ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions.'" (citing Fed. R. Civ. P. 1)). The Court first reaffirmed that "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* at 1949. As a result, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555); *see also id.* at 1950 (Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions."). Second, the Court emphasized that "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than a mere possibility of misconduct, the complaint has alleged -- but it has not shown -- that the pleader is entitled to relief." *Id.* (quotations and alterations omitted).

The Court then set forth a two-step process for assessing the sufficiency of a complaint. The analysis begins "by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* After weeding out conclusory assertions, the court should consider whether the remaining "well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief." *Id.*

The Ninth Circuit has recognized that *Iqbal*'s new pleading standard represents "a significant change, with broad-reaching implications." *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 972 (9th Cir. 2009); *see also Biggs v. Town of Gilbert*, No. CV11-330-PHX-JAT, 2011 WL 1793252, at *1 (D. Ariz. May 11, 2011) ("The standard for deciding Rule 12(b)(6) and Rule 12(c) motions has evolved since the Supreme Court's recent decisions . . . .").[9] In addition, even under pre-*Iqbal* standards, "[a]t the motion to dismiss stage . . . [a] complaint must allege sufficient facts to state the elements of [the relevant] claim."

[9] Because Defendants filed an answer simultaneously with removal of this case to federal court, they have filed this motion pursuant to Federal Rule of Civil Procedure12(c) rather than Rule 12(b). As acknowledged in *Biggs* and held by the Ninth Circuit, the same pleading standard under *Twombly* and *Iqbal* applies to motions filed pursuant to either subsection of Rule 12. *See Biggs*, 2011 WL 1793252, at *1; *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, __F.3d __, 2011 WL 1053366, at * 4, 11 n.4 (9th Cir. Mar. 24, 2011) (stating that the two subsections are "functionally identical" and that the same standard of review is used for both, and applying *Twombly* and *Iqbal* to a 12(c) motion to dismiss).

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Johnson v. Riverside Healthcare Sys., 534 F.3d 1116, 1122 (9th Cir. 2008). After *Iqbal*, therefore, a court must conduct a close comparison between the essential elements of proof and the factual allegations in a complaint to determine whether the plaintiff has adequately stated a claim. *See, e.g.*, *Strand v. John C. Lincoln Health Network, Inc.*, No. CV-10-02112-PHX-NVW, 2011 WL 12543408, at *3 (D. Ariz. Mar. 31, 2011) (dismissing contract causes of action when the plaintiff did not plausibly allege the existence of a contract, an essential element of her claims); *Schayes v. T.D. Serv. Co. of Ariz.*, No. CV-10-02658-PHX-NVW, 2011 WL 1793161, at *6 (D. Ariz. May 11, 2011) (citing *Johnson* and dismissing an accounting cause of action under *Twombly* and *Iqbal* for lack of a plausible key allegation).

II. THE COMPLAINT FAILS TO PLEAD SUFFICIENT FACTS TO SUPPORT ANY OF PLAINTIFF'S LEGAL CLAIMS

Plaintiff's Complaint does not contain enough factual "heft" to support any of Plaintiff's theories of liability. Most of the Complaint consists of formulaic allegations apparently designed to parrot every conceivable iteration of the legal tests that may apply to her claims. *See* First Am. Compl. ¶¶ 39-123. These allegations are precisely the type of summary pleading that *Twombly* and *Iqbal* command district courts to ignore. *See Iqbal*, 129 S. Ct. at 1949 ("Threadbare recitals of the elements of a cause of action . . . do not suffice.") (citing *Twombly*, 550 U.S. at 555). Casting aside the boilerplate paragraphs, Plaintiff's Complaint fails to plead facts that, if taken as true, would satisfy the required elements of Plaintiff's claims.

A. The Complaint Fails to Plead an Adequate Strict Products Liability Claim (Counts I and II)

Three theories of strict products liability are available under Arizona law: failure to warn, manufacturing defect, and design defect. *Gosewich v. Am. Honda Motor Co.*, 153 Ariz. 400, 403, 737 P.2d 376, 379 (1987), *superseded by statute on other grounds*.[10]

[10] It is unclear why Plaintiff asserts a failure to warn claim separately from her claims under Restatement Second of Torts § 402(a), when all strict products liability claims under Arizona law derive from that section of the Restatement. *See, e.g., Dart v. Wiebe*

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Under any of these theories, the plaintiff must show that "(1) the product is defective and unreasonably dangerous, (2) the defective condition existed at the time the product left the defendant's control, and (3) the defective condition is the proximate cause of the plaintiff's injuries." *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1138 (D. Ariz. 2001); *Piper v. Bear Med. Serv., Inc.*, 180 Ariz. 170, 173, 883 P.2d 407, 410 (App. 1993).

1. Plaintiff's Failure to Warn Claim Is Inadequately Pled

To prevail on her failure to warn claim, *see* First Am. Compl. ¶¶ 66-86, Plaintiff must show that the product at issue was defective because it contained an inadequate warning. *See Gosewich*, 153 Ariz. at 403, 737 P.2d at 379 (describing the prima facie elements of a failure to warn claim under Arizona law); *Piper*, 180 Ariz. at 173, 883 P.2d at 410 (same). Here, Plaintiff's Complaint says ***nothing*** about the contents of the FDA-approved Plavix® label included with the product, which is the key source of warnings in a prescription drug case. *See, e.g., Dyer v. Best Pharmacal*, 18 Ariz. 465, 468, 577 P.2d 1084, 1087 (App. 1978) ("The package insert . . . is very relevant. A drug manufacturer has discharged his duty to the public if he has properly warned the administering physician of the contraindications and possible side effects of the drug."). The Complaint ignores the warnings that ***were*** included in the Plavix® package insert, which specifically described the bleeding risk. *See supra* text accompanying note 5. The Complaint does not state how Plaintiff considers the label deficient, and it never states what language the label supposedly should have included. Plaintiff has accordingly failed to allege how the existing Plavix® warnings regarding bleeding failed adequately to convey the risk of the bleeding injury that she allegedly suffered.

Plaintiff also makes no factual allegations to support the required element of causation under the "learned intermediary doctrine," by which the duty to warn in a

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Mfg., Inc., 147 Ariz. 242, 244, 709 P.2d 876, 878 (1985) (stating that liability for strict products liability "exists only if the product was in a 'defective condition unreasonably dangerous'" (quoting Restatement (Second) of Torts § 402(a) (1965)). Regardless of whether the claim is asserted under Count I or Count II of the Complaint, Plaintiff's allegations are insufficient under *Twombly* and *Iqbal* for the reasons set forth above.

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prescription drug case runs to the prescribing physician. *See Dyer*, 18 Ariz. at 468, 577 P.2d at 1087. Under that doctrine, a plaintiff cannot prevail on a failure to warn claim without showing that any purported warning deficiency made a difference in the doctor's decision to prescribe the drug at issue. *See Gosewich*, 153 Ariz. at 379, 737 P.2d at 404 (stating that, to establish the required element of causation, a plaintiff must show that had a proper warning been given, the injury would have been avoided); *see also Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999) (granting summary judgment on a warning defect claim when there was no evidence that the doctor would not have used the medical device at issue if different warnings had been given).[11] Plaintiff's Complaint does not even identify the names of her prescribing doctors, let alone what risk information they supposedly lacked, what an accurate label should have said, and whether an alternative warning would have changed their prescribing behavior. *See Street*, 2009 WL 5216989, at *10-11. Plaintiff's Complaint therefore fails to allege facts supporting a required element of her claim.

2. Plaintiff's Design Defect Claim Is Inadequately Pled

Plaintiff's design defect cause of action, styled as a strict products liability claim pursuant to the Restatement (Second) of Torts § 402(a), likewise fails because it does not adequately allege essential elements of the claim.[12] To make out such a claim, Plaintiff

[11] *See also Lewis v. Abbott Labs.*, No. 08 Civ. 7480, 2009 WL 2231701, at *5 (S.D.N.Y. July 24, 2009) (dismissing an inadequate warning claim under New York law where the complaint did not allege a failure to provide warning to plaintiff's doctors); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991) (applying Louisiana law) ("[T]he plaintiff must show that a proper warning would have changed the decision of the treating physician, *i.e.* that but for the inadequate warning, the treating physician would not have used or prescribed the product."); *Strumph v. Schering Corp.*, 626 A.2d 1090, 1090 (N.J. 1993) (adopting the reasoning of the dissent in the lower court, which found that "plaintiff must show that adequate warnings would have altered her doctors' decision to prescribe [a drug]") (*Strumph v. Schering Corp.*, 606 A.2d 1140, 1148 (N.J. Super. Ct. App. Div. 1992) (Skillman, J., dissenting)).

[12] The substantive allegations of Plaintiff's "Restatement Second of Torts 402(a)" cause of action appear to assert a design defect claim, and nothing in the Complaint suggests an attempt to plead manufacturing defect. A manufacturing defect claim would fail in any event because Plaintiff nowhere identifies an error in the manufacturing process for Plavix® or how a resulting defect caused her alleged injury. *See Brady v. Melody Home Mfr.*, 121 Ariz. 253, 256, 589 P.2d 896, 899 (App. 1978), *overruled on other grounds by Dart*, 147 Ariz. at 246, 709 P.2d at 880 (describing a manufacturing

must show that Plavix® was unreasonably dangerous due to a defective design and that the defective design is the proximate cause of Plaintiff's injuries. *See Cloud*, 198 F. Supp. 2d at 1138; *Piper*, 180 Ariz. 170 at 173, 883 P.2d at 410. The Complaint, however, does not say what about the Plavix® design was defective. *See Dart*, 147 Ariz. at 244, 709 P.2d at 878 ("[T]he law does not impose liability for every injury caused by a product. Liability exists only if the product was in a defective condition unreasonably dangerous." (internal quotation omitted)). Given that Plaintiff's only alleged injury is a bleeding event, *see* First Am. Compl. ¶ 31, and that ***all*** antiplatelet drugs can cause this side effect, *see supra* text accompanying note 5, it is difficult to discern what defect Plaintiff could claim at all.

Plaintiff also has failed to demonstrate any defect in Plavix® under either of the two tests used in Arizona.[13] She pleads ***no*** facts demonstrating how or why an ordinary consumer would expect Plavix to perform differently than it did when she took it (the "consumer expectation test"), and she pleads ***no*** facts purporting to show how the risks of Plavix® outweighed its benefits (the "risk/benefit test"). *See Dart*, 147 Ariz. at 245, 709 P.2d at 876; *see also Golonka*, 204 Ariz. at 581 n.2, 65 P.3d at 962 n.2 (listing factors such as the usefulness of the product and the avoidability of injury by care in use of the product, including the effect of warnings, for consideration under the risk/benefit test). The Complaint fails to allege a factual basis for liability no matter the test applied.[14]

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defect as resulting when "something goes wrong" in the physical production process, causing the particular product taken or used by the plaintiff to malfunction in some way that the manufacturer did not intend and the plaintiff did not expect); *see also Hearn v. R.J. Reynolds Tobacco Co.*, 279 F. Supp. 2d 1096, 1115 (D. Ariz. 2003) (dismissing a manufacturing defect claim sounding in negligence when the complaint failed to allege injury suffered because the product was not in the condition intended by the defendants).

[13] While the consumer expectation test may be used in design defect cases, it "has limited utility as the consumer would not know what to expect, because he would have no idea how safe the product could be made." *See Golonka v. Gen. Motors Corp.*, 204 Ariz. 575, 531, 65 P.3d 956, 962 (Ariz. 2003) (internal quotation omitted)). When application of the test is thus unfeasible or uncertain, as it may be deemed in case involving a prescription drug, "courts additionally or alternatively employ the risk/benefit analysis to determine whether a design is defective and unreasonably dangerous." *See id.*

[14] *See Frey v. Novartis Pharms. Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009) (dismissing a design defect claim "because plaintiffs . . . have not alleged any facts that

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B. The Complaint Fails to Plead an Adequate Emotional Distress Claim (Counts III and IV)

Arizona courts cite the Restatement for the three required elements of a claim for intentional infliction of emotional distress: "***first***, the conduct by the defendant must be 'extreme' and 'outrageous'; ***second***, the defendant must either intend to cause emotional distress or recklessly disregard the near certainty that such distress will result from his conduct; and ***third***, severe emotional distress must indeed occur as a result of defendant's conduct." *Ford v. Revlon, Inc.*, 153 Ariz. 38, 43, 734 P.2d 580, 585 (1987) (emphasis in original); *Midas Muffler Shop v. Ellison*, 133 Ariz. 194, 197, 650 P.2d 496, 499 (App. 1982) (noting that Arizona has adopted Restatement (Second) of Torts § 46 (1965)). Plaintiff's Complaint lacks any statement of what constitutes Defendants' "outrageous" conduct. *See* First Am. Compl. ¶¶ 96-100; *see also Mintz v. Bell Atl. Sys. Leasing Int'l, Inc.*, 183 Ariz. 550, 554, 905 P.2d 559, 563 (App. 1995) ("A plaintiff must show that the defendant's acts were so outrageous in character and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious and utterly intolerable in a civilized community." (internal quotation omitted)); *Grundy v. JPMorgan Chase Bank, N.A.*, No. CV10-1542-PHX-DGC, 2011 WL 1671956, at *4 (D. Ariz. May 4, 2011) (dismissing an intentional infliction of emotional distress claim when the plaintiff pled no conduct that was plausibly extreme and outrageous). Nor does the Complaint suggest that the conduct alleged -- *i.e.*, over-promotion of Plavix® to doctors -- was intended to cause or recklessly caused emotional distress in Plaintiff, when there are no allegations that Plaintiff ever saw the promotions or studies cited. The Complaint further leaves unclear what ***severe*** emotional distress Plaintiff allegedly suffered. *See* Restatement (Second) of Torts § 46 ("The law intervenes only where the distress inflicted is so severe that no reasonable man could be expected to endure it.").[15] Lacking support

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would permit the Court to conclude that there was a defect in the design or formulation of [the drug]"); *Lewis*, 2009 WL 2231701, at *4 (dismissing a design defect claim where the plaintiff nowhere alleged a feasible safer design).

[15] *See Midas Muffler Shop*, 133 Ariz. at 199, 650 P.2d at 501 (citing examples of emotional distress considered severe by the courts, including fright resulting in the

for all of these elements, the Complaint fails to state a claim for intentional infliction of emotional distress.

Plaintiff's claim for negligent infliction of emotional distress stretches the bounds of legitimacy even more. Under Arizona law, Plaintiff may recover on such a claim only if she shows that she suffered mental distress as a result of Defendant's actions, manifesting itself as physical injury or "long-term physical illness or mental disturbance." *See Monaco v. Healthpartners of S. Ariz.*, 196 Ariz. 299, 303, 995 P.2d 735, 739 (App. 2000).[16] She must show, moreover, that Defendants "should have realized that [their] conduct involved an unreasonable risk of causing the distress . . . [and] should have realized that the distress, if it were caused, might result in illness or bodily harm." *Deno v. Transamerica Title Ins. Co.*, 126 Ariz. 527, 529, 617 P.2d 35, 37 (App. 1980). The Complaint makes no suggestion of an emotional injury that Plaintiff might have suffered, much less a physical manifestation of her distress that would allow recovery. *See Hearn*, 279 F. Supp. 2d at 1116 (dismissing a negligent infliction of emotional distress claim when the plaintiffs failed to plead physical injury). Her claim therefore fails.

C. The Complaint Fails to Plead an Adequate Negligence Claim (Count VI)

To prevail under a negligent manufacture or design theory, Plaintiff "would have to prove everything he would need to prove under a strict liability theory plus [s]he would have to prove that the defendant[s] knew or should have known that [the product] was unnecessarily dangerous." *Gomulka v. Yavapai Mach. & Auto Parts, Inc.*, 155 Ariz. 239, 243, 745 P.2d 986, 990 (App. 1987); *see also Dart*, 147 Ariz. at 247, 248-49, 709 P.2d at 881, 882-83 ("For a plaintiff to prove negligence he must prove that the designer or

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premature birth of a dead baby; extreme shock and hysteria and a breakdown of physical and emotional well-being that left the plaintiff unable to perform her job; and severe headaches and stress that ultimately required hospitalization).

[16] Arizona also allows the claim where a person closely related to the plaintiff witnessed the injury, suffered mental anguish manifested as physical injury, and was within the "zone of danger." As the Complaint nowhere mentions such a person, Plaintiff presumably does not intend to proceed under this theory of the claim.

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manufacturer acted unreasonably at the time of manufacture or design of the product. . . . The question is whether a reasonable manufacturer, with knowledge of such dangers, nevertheless would have put the product on the market."). Because Plaintiff has failed to plead a strict liability manufacturing or design defect claim adequately, *see supra* pp. 11-12, it follows that she has failed to plead negligent design adequately. *See Gomulka*, 155 Ariz. at 243, 745 P.2d at 990 (describing a negligent design claim as "redundant" when the plaintiff could not make out a strict liability claim).

A negligent failure to warn claim fails because Plaintiff alleges no facts to support causation. *See Cloud*, 198 F. Supp. 2d at 1138 (noting that, under Arizona law, both strict products liability and negligence claims include a prima facie element of causation). The boilerplate variations on the elements of duty, breach, and causation recited in the Complaint are not ***factual*** allegations and are therefore entitled to no weight. *See* First Am. Compl. ¶¶ 110-11; *Iqbal*, 129 S. Ct. at 1949-50. And, since Plaintiff does not link the allegedly misleading promotional materials and the two journal articles she cites with Plaintiff's prescription for Plavix®, *see supra* pp. 4-5, there is no causal connection between those items and Plaintiff's alleged injuries.

D. The Complaint Fails to Plead an Adequate Fraud or Misrepresentation Claim (Counts V, VII, and VIII)

Plaintiff's fraud and misrepresentation claims fail under both Rule 8(a) and 9(b). For claims involving fraud or mistake, including false representation premised on negligence, the plaintiff must comply with Rule 9(b)'s additional pleading requirement that "the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P 9(b); *see Hearn*, 279 F. Supp. 2d at 1115. To show particularity, "the plaintiff must set forth what is false or misleading about a statement, and why it is false," and must further allege the plaintiff's reasonable reliance on the defendant's misrepresentations. *See id.* at 1113-14; *see also Reiniger v. W.L. Gore & Assoc., Inc.*, No. CV-09-8185-PCT-PGR, 2010 WL 1948588, at *3 (D. Ariz. May 12, 2010) ("Rule 9(b), which applies to both common law fraud and statutory causes of action based on fraud,

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mandates that fraud claims be pleaded with particularity, i.e. that averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged."). Because complaints alleging such claims must comply with both Rules 8(a) and 9(b), the Ninth Circuit has held that "claims of fraud or mistake . . . must, in addition to pleading with particularity, also plead plausible allegations" under the *Twombly*/*Iqbal* standard. *See Cafasso*, 2011 WL 1053366, at * 4.

As the New Jersey federal court found in dismissing fraud and negligent misrepresentation claims based on virtually identical allegations, Plaintiff's Complaint fails to meet the pleading requirements of Rule 8(a), much less "the rigors of Rule 9(b)." *See, e.g.*, *Street*, 2009 WL 5216989 (granting dismissal under Rule 8(a)); *Begley v. Bristol-Myers Squibb Co.*, Civil Action No. 06-6051 (FLW), 2009 WL 5216967 (D.N.J. Dec. 30, 2009) (granting dismissal under Rule 9(b)). Plaintiff has failed to plead any facts that could support a nexus between Defendants' purportedly deceptive practices and Plaintiff's injuries. *See Street*, 2009 WL 5216989, at *10; *Begley*, 2009 WL 5216967, at *9. She has not identified any specific advertisement that she or her prescribing physicians viewed, *see Street*, 2009 WL 5216989, at *11, nor has she alleged that her physicians personally received a misrepresentation of fact from Defendants and relied on that misrepresentation in deciding to prescribe Plavix® to Plaintiff, *see Begley*, 2009 WL 5216967, at *9. As the New Jersey Court further noted, "these factual allegations are not of the type of facts that are within the control of, and therefore subject to concealment by Defendants. Indeed, these important details regarding misrepresentations made to, and relied upon by, Plaintiffs and their physicians are within Plaintiffs' ken, but are nowhere to be found" in the complaints. *See id.* at *10; *see also Strand*, 2011 WL 1253408, at *3 (in granting a motion to dismiss under *Twomby* and *Iqbal*, noting that "[t]his is not a case in which the facts necessary to make [the plaintiff's] claim plausible are in the defendant's sole possession").

For the same reasons given by the New Jersey Court, Plaintiff has failed to state claims for fraud or negligent misrepresentation.

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E. The Complaint Fails to Plead an Adequate Warranty Claim (Counts IX and X)

Plaintiff's warranty claims rest solely on a few scant paragraphs stating legalese without any factual allegations in support. An express warranty claim requires a showing that the seller made an affirmation of fact or promise that became the basis of an individual bargain. *See Tri-City Prop. Mgmt. Servs., Inc. v. Research Prods. Corp.*, 149 Ariz. 596, 599, 721 P.2d 144, 147 (App. 1986) (citing Ariz. Rev. Stat. § 47-2313); *see also* Ariz. Rev. Stat. Ann. § 47-2313 cmt. 1 ("Express warranties rest on 'dickered' aspects of the individual bargain . . . ." (internal quotation omitted)). Plaintiff has identified no express warranty that Defendants allegedly made, nor made any suggestion as to what or how a bargain was struck. Her express warranty claim thus falls far short.[17]

Plaintiff's implied warranty claims fail under the strict products liability analysis above because, "in Arizona, when a complaint alleges product liability claims under theories of both breach of implied warranties and strict liability, those theories merge." *Hearn*, 279 F. Supp. 2d at 1103; *see also Flory v. Silvercrest Indus., Inc.*, 129 Ariz. 574, 579, 633 P.2d 383, 388 (1981) ("In Arizona we have recognized that an action styled as 'breach of implied warranty' to recover damages for physical injury to person or property is in essence an action based on strict liability in tort."); *Scheller v. Wilson Certified Foods, Inc.*, 114 Ariz. 159, 162, 559 P.2d 1074, 1076 (App. 1977) ("[T]he theory of liability under implied warranty has been merged into the doctrine of strict liability in tort, so that it is on this latter doctrine that the plaintiff's claim must stand or fall."). Plaintiff's failure to make out a strict liability claim is thus fatal to any implied warranty claim.

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[17] *See Burks v. Abbott Labs.*, 639 F. Supp. 2d 1006, 1018 (D. Minn. 2009) (dismissing an express warranty claim when the plaintiff failed to identify any express warranty made by the defendants); *Heisner ex rel. Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, at *9 (N.D. Ill. July 25, 2008) (dismissing an express warranty claim and stating that "Plaintiff has not specified any particular affirmation, promise, description, or sample that formed part of the basis of his bargain with Defendant. He thus fails to put the Defendant on notice as to the substance of his claim.").

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CONCLUSION

For all the reasons set forth herein, Defendants respectfully request that the Court grant their motion pursuant to Federal Rules 12(c), 8(a), and 9(b) for failure to state a claim upon which relief can be granted.

DATED this 3rd day of June, 2011.

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CERTIFICATE OF SERVICE

I hereby certify that on the 3rd day of June, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record. A copy of the foregoing was also mailed on the 3rd day of June, 2011, to:

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